Questions for CLIAC Consideration

ELECTRONIC HEALTH RECORD (EHR)

Questions for CLIAC Consideration Electronic Health Record (EHR)

1. *The CLIA interpretive guidelines for test ordering and result reporting were revised to facilitate the electronic exchange of laboratory information.* [1]

   Are there remaining gaps pertaining to CLIA that need to be addressed to support implementation of electronic health records (EHRs)?

[1] March 1, 2010 Survey and Certification Letter (CMS S&C-10-12-CLIA)

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2. *The HHS certification criteria for EHRs at 42CFR170.302(h)(2) includes requirements for display of test report information as specified by CLIA at 42CFR493.1291(c)(1) through (7).*

   Are these test report elements adequate for the correct interpretation and use of patient test results by a healthcare provider using an EHR? Is additional information needed for this purpose?

Requirements and examples on next slide

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Requirements specified by CLIA at 42CFR493.1291(c)(1) through (7) include:

- *Patient name and ID number or a unique patient identifier and ID number*
- *Name and address of the lab location where the test was performed*
- *Test report date*
- *Test performed*
- *Specimen source, when appropriate*
- *Test result and, as applicable, the units of measurement or interpretation, or both*
- *Information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability*

Examples of other test report elements may include:

- *Elements required as part of the test request (specimen collection date and time, gender, age or D.O.B)*
- *Purpose of the test – e.g. screening, confirmatory, diagnostic*
- *Method of testing and limitations*
- *Reference ranges*
- *Critical result flags*
- *Unique considerations for interpretive reports*
- *Others?*

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3. *What enablers and barriers exist for the use of HHS-certified record systems in healthcare to display laboratory test results?*

Examples may include:

- *Cost*
- *Incentives*
- *Regulations*
- *Interoperability with healthcare information system interfaces*

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4. ***In what areas can the laboratory community provide input with respect to the implementation of EHRs and ONC activities?***

   Examples may include:

   - *Harmonization of CLIA with HHS EHR regulations*
   - *EHR functionalities that meet the HHS EHR certification criteria*
   - *Oversight of EHR certification*
   - *Quality measures for the effectiveness of laboratory test report displays*
   - *Personal Health Records (PHR)*
   - *FDA's draft guidance for mobile medical applications*
   - *Others?*

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5. *What mechanisms could be used by HHS to communicate information and provide opportunity for the laboratory community to contribute on issues related to the implementation of EHRs?*